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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,095	11/22/2000	Aaron I. Vinik	05216.00001	5818

22907 7590 04/21/2003

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WASHINGTON, DC 20001

EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1653

19

DATE MAILED: 04/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/717,095

Applicant(s)
Vinik et al.

Examiner
HOPE ROBINSON

Art Unit
1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 26, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

Art Unit: 1653

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 30, 2002 has been entered.

Claim Disposition

2. Claims 1-24 are pending.
3. Applicant is reminded of the continuing obligation under 37 CFR 1.56 to timely apprise the Office of any litigation information, or other prior or concurrent proceeding, involving Patent No. 5,840,531, which is material to patentability of the claims under consideration in this reissue application. This obligation rests with each individual associated with the filing and prosecution of this application for reissue. See MPEP 1404, 1442.01 and 1442.04.

Art Unit: 1653

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 12, 17, 24 remain rejected under 35 U.S.C. 112 first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record.

The Basis For Non-Statutory Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

Art Unit: 1653

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-24 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-49 of copending Application No. 09/659,379. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application are directed to a recombinant construct for expression of INGAP which comprises a nucleotide sequence that encodes the amino acids set forth in SEQ ID NO: 6. Note that the present application is directed to an isolated DNA molecule which encodes an INGAP protein set forth in SEQ ID NO: 2 and both sequences are identical with the exception of one residue (SEQ ID NO: 6 has an additional Methionine in the beginning of the sequence). Furthermore, the present application and copending application both claim probes, primers and have claims directed to antisense strands

Art Unit: 1653

which would render each other obvious. Although the claims in the two applications are not identical the claimed subject matter in both applications are an obvious variation of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Applicant's arguments filed on October 30, 2002 in Paper No. 17 has been fully considered however, was not persuasive. The rejections under 35 U.S.C. 112, first paragraph remains, however, based on the interview on June 21, 2002 the amendments discussed will obviate this ground of rejection (see the attached summary). The arguments presented in the response will be addressed in this office action. The response on page 2 asserts that the specification teaches that INGAP stimulates islet cell neogenesis and that the PTO requires that the specification teach the biochemical mechanism by which INGAP stimulates islet cell neogenesis. This assertion is not correct as the rejection set forth that applicant needs to have functional language recited in the claims as there are claims directed to fragments (see for example claim 12). The response also asserts that claims 12, 17 and claims with similar language are directed to nucleotide sequences which encode a specific amino acid sequence (see also claim 24). This assertion is not persuasive as it is unclear whether the fragments claimed encode the same protein as the full length sequence, thus, having the same function. As "portions/fragments" of the sequence is claimed and there's no indicia from the claims or specification that the same function is achieved with the fragments/portions of the sequence, the

Art Unit: 1653

rejection remains. If the invention is not adequately described then it doesn't demonstrate possession (see the Written Description Guidelines).

Applicant's response on page 3 states that claims 17 and 24 do not improperly recapture subject matter surrendered during prosecution. It is stated that the size of the nucleotide sequence recited was not altered, thus applicants never surrendered subject matter including portions of INGAP. This argument is not persuasive as the office action in the parent file (08/709,662) stated that applicant is only enabled for the specific nucleic acid disclosed in the specification that encode specific polypeptides, thus, applicant was not enabled for portions/fragments of the claimed sequence. Thus, the rejection under 35 U.S.C. 251 remains.

The response on page 4 requests the withdrawal of the rejection under 35 U.S.C. 103, Obvious-type Double Patenting because it is stated that the '379 application requires that the signal sequence be absent in nucleic acid constructs which is not taught or suggested in the subject claims. The rejection of record sets forth that the two applications although differ in scope are obvious variations of each other with regard to the claimed DNA encoding proteins that are substantially homologous and claims to probes, primers etc. as stated above and in the previous office action. Thus, this ground of rejection has been maintained. It is noted that applicant has filed a terminal disclaimer in the copending application which has recently been allowed. Once the copending application becomes a patent, the rejection will no longer be provisional. It is noted that applicant filed a terminal disclaimer, however, as the terminal disclaimer is not proper the rejection remains.

Art Unit: 1653

Conclusion

8. No claims are allowable.

9. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

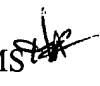
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 5:30 P.M. (EST).

Art Unit: 1653

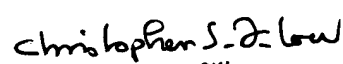
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS 

Patent Examiner


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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